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Effect of a multifactorial intervention on the increase in physical activity in subjects with type 2 diabetes mellitus: a randomized clinical trial (EMID Study)

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Abstract

Background: Regular physical activity is essential for metabolic control in type 2 diabetes mellitus.

Aims: The aim of this study was to assess the short and long-term impact of a multifactorial intervention on physical activity and clinically relevant biochemical parameters in patients with type 2 diabetes mellitus.

Methods: This randomised, controlled clinical trial (NCT02991079) included two parallel groups aged 25–70 years from a primary care health centre in Salamanca, Spain. The subjects were assigned randomly (1:1) to control and intervention groups, using Epidat 4.0 software. Both were counselled on the importance of physical activity and maintaining a healthy diet. The intervention group also took five low–moderate intensity 4 km nurse-guided walks, received a smartphone application to promote healthy habits and attended a diet workshop. Physical activity was measured objectively using a pedometer and subjectively using a shortened international physical activity questionnaire (at baseline, 3 and 12 months).

Results: In total, 204 subjects were included (mean age 60.6 years, 45.6% were women). After 3 months, relative to the control group, the intervention group increased their daily number of steps by 1852, aerobic steps by 1623, distance walked by 994 m, and total metabolic equivalent minutes per week by 1297 and decreased sedentary time by 34.3 minutes per day. Differences from baseline persisted at 12 months, including mean increases of 1141 daily steps, 917 aerobic steps, and 1065 total metabolic equivalent minutes per week in the intervention group relative to the control group ($P<0.05$ for all).

Conclusions: The success of this multifactorial intervention should help inform future clinical approaches and application designs towards managing type 2 diabetes mellitus and improving patient outcomes.

Keywords

Type 2 diabetes, physical activity, walking, health education, information and communication technology

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Introduction

An increase in physical activity (movement that increases energy use)[1] is essential for regulating type 2 diabetes mellitus (T2DM).[2] Several studies conducted in patients with T2DM[3,4] have shown that physical activity is associated with a decreased risk of having a cardiovascular event (coronary artery disease, acute myocardial infarction and/or stroke) as it affords greater blood glucose control, improvement in lipid profile, weight loss[5] and decreased blood pressure.[6] However, despite this evidence, it is estimated that only 33.8%[7] of patients follow the recommendations of

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the American Diabetes Association to perform aerobic physical activity of moderate to vigorous intensity (50–70% of maximum heart rate)[8] such as walking, cycling, or swimming, for at least 150 minutes per week, practised at least three times per week, with no more than two consecutive days with no physical activity.[1]

Aerobic physical activity is defined as exercise that primarily uses the aerobic energy-producing systems; it can improve the capacity and efficiency of these systems and cardiorespiratory endurance.[9] It has both short-term (increased glucose absorption in active muscle tissues and decreased glucose formation in the liver) and long-term benefits (improved insulin action and blood glucose control and decreased systolic blood pressure).[10] Walking is the most popular and preferred physical activity among patients with T2DM.[11] This is because it can be adapted to the capacity of each individual,[12] carries a low risk of injury, and does not require specific skills or special infrastructure.[13] The joint position statement from the American College of Sports Medicine and the American Diabetes Association,[10] based on a systematic review carried out by Bravata et al.,[14] advises patients with T2DM to set and achieve a daily goal of a number of steps, such as 10,000 steps per day, as it is an important predictor of increased physical activity.

To increase the number of daily steps, compared to a baseline visit, was the objective of the studies carried out by Fayehun et al.[15] and Tudor-Locke et al.;[16] however, multifactorial interventions combining diet and exercise have given the best results in terms of disease management for this population.[17,18]

Towards this end, there has been a sharp increase in health-related smartphone applications (apps) over the past decade.[19] Thus, recent studies, such as that by Bonn et al.[20] have used smartphone apps to encourage and enable lifestyle modifications for patients with T2DM. However, in their systematic review, Schoeppe et al.[19] concluded that these apps are more effective when combined with other intervention strategies (multicomponent intervention), such as physical education or counselling sessions.

Therefore, this study aimed to assess the effect of a multifactorial intervention approach based on a smartphone app, walking, and a diet workshop on physical activity in subjects with T2DM.

Methods

Study design

The study 'Effectiveness of a multifactorial intervention in diabetics' (EMID)[21] is a randomised, controlled clinical trial with two parallel groups and a 12-month follow-up period. The study was conducted in a primary healthcare setting at La Alamedilla research unit, which belongs to the Network for Research on Preventive Activities and Health Promotion (REDIAPP) and to the Biomedical Research Institute of Salamanca (IBSAL).

Participants

Study subjects were selected by stratified random sampling among patients with T2DM attending La Alamedilla healthcare centre to form three groups according to age: 25-35, 36-50 and 51-70 years. Inclusion criteria: patients of both sexes with TDM2, aged 25-70 years who, after receiving information about the study, agreed to participate and signed an informed consent document. To be classified, a patient with TDM2 must meet the following criteria: fasting plasma glucose above 126 mg/dL or 2-hour plasma glucose above 200 mg/dL during an oral glucose tolerance testing (using a glucose load containing the equivalent to 75 g anhydrous glucose dissolved in water) or glycosylated haemoglobin over 6.5%; in all cases, these test were repeated to confirm the results in the absence of unequivocal hyperglycaemia. Additionally considered as having TDM2 were patients with the classic symptoms of hyperglycaemia or hyperglycaemic crisis, i.e. random plasma glucose above 200 mg/dL.[22]

Exclusion criteria: a history of cardiovascular events, musculoskeletal disease preventing ambulation or clinically documented neurological and/or neuropsychological disease that would prevent visits to the healthcare centre.

Interventions

Specific interventions and counselling appointments were performed by three nurses at the health centre, who have previously been instructed in two one-hour training classes on how to carry out each session. The sessions were standardised, describing in each one what points should be treated, in what order and for how long.

Intervention common to both groups. All study participants received standardised counselling for 10 minutes on physical activity and a healthy diet. Counselling on physical activity lasted for 5 minutes and included advice on compliance with the current international recommendations (to walk at least 10,000 steps daily and avoid a sedentary lifestyle). Diet counselling also lasted for 5 minutes and focused on the use of the plate method and recommendations to adhere to the Mediterranean diet. All participants were given a leaflet as support.

Interventions specific to the study group. Groups of 10 participants underwent a multifactorial intervention, guided by nurses from the healthcare centre, consisting of five heart-healthy walks, use of a smartphone app, and a diet workshop.

Aerobic walks. Patients engaged in heart-healthy walks once per week for five consecutive weeks. Subjects walked

4 km on level ground, with the healthcare centre as the starting and finishing point, and accompanied at all times by two nurses. Warming-up exercises were done for 10 minutes prior to these walks, which were followed by 10 minutes of stretching and relaxation. In order to make the walks qualify as aerobic exercise (50–70% maximum heart rate),[8] participants were divided into two groups depending on intensity. The approximate speed of the group walking at moderate intensity (5 metabolic equivalents (METs)) was 6 km/hour compared to 3–4 km/hour in the group walking at low intensity (2.5 METs).

EVIDENT II application. In a one-hour group workshop, subjects were instructed in the use of the EVIDENT II app (intellectual property registry no. SA-81-14) used in prior studies[23] and designed to increase physical activity and adherence to the Mediterranean diet. EVIDENT II is a smartphone app resulting from a collaboration between the company CGB and the research group GIAPCyL of REDIAPP (RD12/0005/0004) through the Infosalud Foundation. It was designed by software engineers with input from dieticians and experts in physical activity. The app counts the number of daily steps and subjects recorded information on other types of physical activity performed when the device could not be used (e.g. swimming). At the end of each day, the app assessed the physical activity levels and provided recommendations for increasing those levels if need be. In addition, the application was configured to include data from each participant (age, sex, weight and height) to tailor the diet-based information with the aim of encouraging healthy eating choices.

The smartphone was returned at 3 months, at the follow-up visit common to both groups. Subsequently, the stored information was downloaded and assessed for adherence to the app according to the number of days of use.

After this 3-month intervention period, the subjects did not have access to the EVIDENT II app, because it was not free online.

Outcome measures and follow-up

All variables were collected at baseline, 3 and 12 months after the initial intervention to assess the effect of this multifactorial approach.

Variables related to physical activity

Objective quantification of physical activity: HJ-321 Triaxis pedometer. Physical activity was objectively recorded for seven consecutive days using a digital pedometer with two piezoelectric sensors (Omron HJ-321 Triaxis) placed on the right side of the waist. This pedometer has previously been validated[24] and records mean daily steps, aerobic steps,[25] distance travelled and calories consumed. Aerobic steps are defined as 60 steps per minute for more than 10 consecutive minutes. However, if a pause shorter than one minute was made after walking continuously for more than 10 minutes, this was considered to be part of a continuous walk.

Subjective quantification of physical activity: short version of international physical activity questionnaire. Physical activity was self-reported by the study subjects using a short version (translated into Spanish) of the international physical activity questionnaire (IPAQ-S).[26] The IPAQ-S assesses the frequency, duration and intensity of physical activity performed in the last 7 days, as well as the time spent sitting during the work day, and classifies activity based on type (walking, moderate-intensity and vigorous-intensity activities) and on the energy expenditure estimated for each of type (3.3, 4.0, and 8.0 METs, respectively). Thus, the IPAQ-S enables calculating the METs-min/week and for stratifying subjects into three activity levels (low, intermediate and high) and as active (physical activity for at least 30 minutes 5 days per week or high-intensity aerobic physical activity for at least 20 minutes 3 days per week)[27] or sedentary (physical activity for less than 30 minutes 5 days per week or high-intensity aerobic physical activity for less than 20 minutes 3 days per week).

Clinically relevant measures. Other variables measured at the beginning of the study and at the follow-up visits included drug use, blood pressure, body mass index (BMI) and biochemical parameters (fasting plasma glucose, glycated haemoglobin, triglycerides, total serum cholesterol, low-density lipoprotein (LDL) cholesterol and high-density lipoprotein-cholesterol levels). Data collection procedures were performed as previously described.[21]

Sample size

The sample size was estimated a priori taking into account the expected increase in physical activity, as measured through the number of daily steps. Assuming a standard deviation of 4500 steps per day measured with a pedometer, 196 subjects (98 per group) were required to detect an increase of 1850 steps per day in the intervention group (IG) versus the control group (CG), with an expected loss to follow-up rate of 5%. Recruitment of 204 subjects was therefore considered adequate for detecting clinically relevant differences in the main study variables.

Screening and randomization

Participants were randomly divided into the IG (n=102) or the CG (n=102) in a 1:1 ratio. The randomisation sequence was generated by an independent researcher using Epidat 4.0 software (Department of Health, Government of Galicia, Spain) and it was kept blinded until assignment to the group (Figure 1).

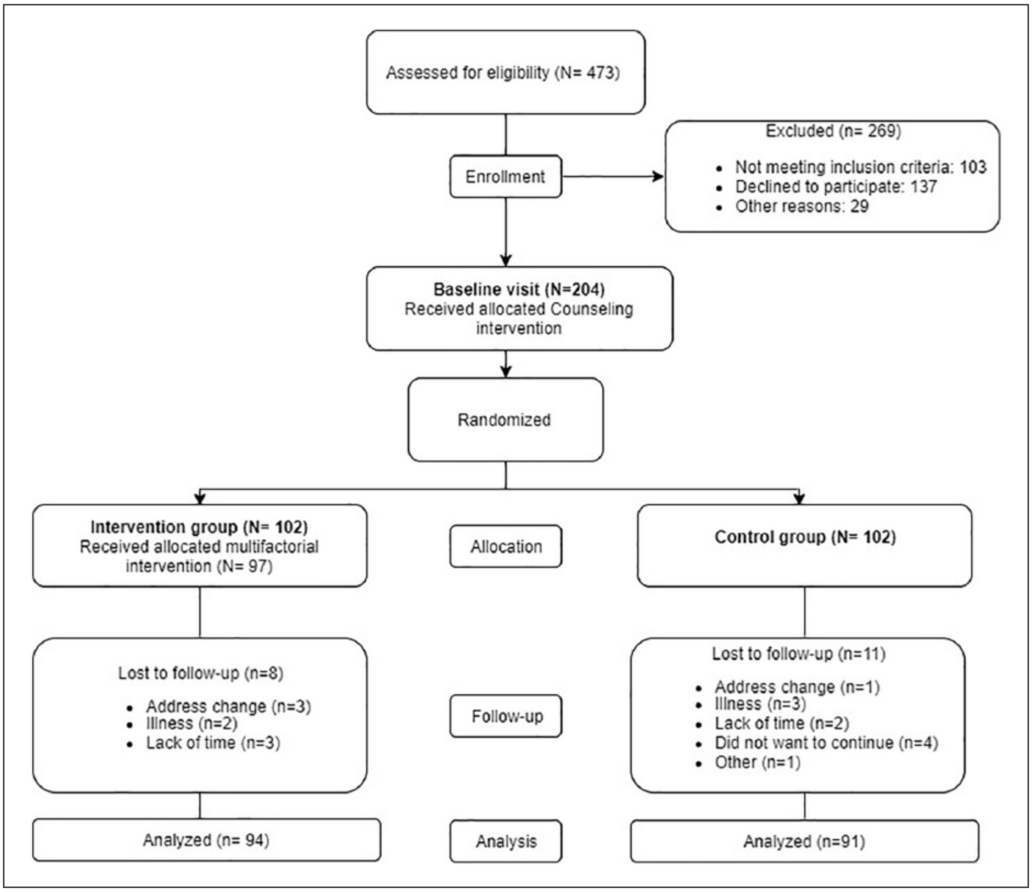

Figure 1. Flow diagram depicting study enrolment and completion.

Ethical considerations

The study was approved by the clinical research ethics committee of the health area of Salamanca on 28 November 2016. All procedures were performed in accordance with the ethical standards of the institutional research committee and with the 2013 Declaration of Helsinki.[28] All patients signed written informed consent documents prior to participation in this study.

Statistical analyses

Analyses of the data were performed on an intent-to-treat basis. Variables are given as mean ± standard deviation. The chi-squared test was used to analyse associations between the independent categorical variables and the Student's *t*-test for paired data was used to assess changes within the same group between the quantitative variables. The Student's *t*-test for independent samples was used to compare the means of the two groups. An analysis of covariance (ANCOVA), after adjusting for the baseline measurement of each variable, was used to compare changes in the IG and CG. An analysis of variance (ANOVA) of repeated measures using the generalised linear model was used to compare the effects of the intervention between the IG and the CG as well as between the visits (baseline, 3 and 12 months) on the variables related to physical activity (mean steps per day, aerobic steps, METs-min/week and sedentary time (minutes per day)). When significant differences were found, the Bonferroni test was used for multiple comparisons. A P value less than 0.05 was considered statistically significant. Data were analysed using the statistical software SPSS for Windows version 24.0 (IBM Corp., Armonk, NY, USA).

Results

Baseline and follow-up characteristics

A total of 473 subjects were selected by stratified random sampling among the 1291 patients with T2DM aged 25–70 years attending the La Alamedilla healthcare centre. Of these, 103 subjects were excluded because they did not meet the inclusion criteria, 137 did not agree to take part and 29 were excluded for other reasons. Finally, 204 subjects were recruited into the study and 185 participants (90.7%) completed the study. The reasons for dropping out are detailed in the flowchart in Figure 1.

Table 1 presents the baseline characteristics of the participants. The CG was aged 60.4 ± 8.4 years with 41

Table 1. Baseline characteristics of the study population (*N*=204).

	Control group (102)	Intervention group (102)	*P* value
Age (years), median (IQR)	60.4 (8.4)	60.8 (7.8)	0.836
Gender (female), *n* (%)	41 (40.2)	52 (51.1)	0.080
Work situation, *n* (%)			0.914
Works outside home	41 (40.2)	29 (28.4)	
Homemaker	18 (17.6)	24 (23.5)	
Retired	34 (33.3)	44 (43.1)	
Unemployed	7 (6.8)	5 (4.9)	
Educational level, *n* (%)			0.943
University studies	17 (16.7)	17 (16.7)	
Middle or high school	33 (32.4)	37 (36.3)	
Elementary school	52 (51.0)	48 (47.1)	
Factors of CVR, *n* (%)			
Smoking	26 (25.5)	10 (9.8)	0.130
Cigars in smokers, *n*	20.4 (13.8)	19.2 (14.5)	0.634
Hypertensive	59 (57.8)	56 (54.9)	0.674
Dyslipidaemic	57 (55.9)	59 (57.8)	0.779
Clinical variables			
Glycated haemoglobin, %	6.8 (1.2)	6.9 (1.2)	0.478
Glucose (mg/dl)	123.3 (36.5)	127.0 (35.4)	0.458
Postprandial glucose, mg/dl	147.6 (35.5)	149.2 (39.0)	0.762
Total cholesterol, mg/dl	176.4 (31.7)	178.8 (30.3)	0.586
LDL-cholesterol, mg/dl	100.4 (28.6)	101.8 (30.0)	0.738
Body mass index, kg/m^2	30.3 (5.6)	29.5 (4.2)	0.266
Waist Circumference, cm	104.9 (13.1)	102.2 (11.5)	0.113
Systolic blood pressure, mmHg	135.0 (33.2)	133.2 (15.9)	0.612
Diastolic blood pressure, mmHg	80.5 (9.6)	80.8 (9.0)	0.787
Medication use, *n* (%)			
Antihypertensive drugs	55 (53.9)	53 (52.0)	0.241
Lipid-lowering drugs	59 (57.8)	58 (56.9)	0.389
Insulins	18 (17.6)	12 (11.8)	0.238
Metformin	81 (79.4)	82 (80.4)	0.862

Variables are given as mean ± standard deviation.
A chi-square test was used to analyse the association between independent categorical variables and a Student's *t*-test for independent samples was used in quantitative variables.
P value differences between control group and intervention group.
IQR: interquartile range; SD: standard deviation; CVR: cardiovasular risk; LDL: low-density lipoprotein.

(40.2%) women. The IG was aged 60.8 ± 7.8 years with 52 (51.1%) women. There were no significant differences at the baseline visit between the groups in terms of demographic or clinical characteristics.

Table 2 contains the pedometer measurements and self-reported physical activity data using the IPAQ-S at baseline and the follow-up visits (3 and 12 months). At baseline, the mean daily steps were 8288 in the CG and ,778 in the IG. METs-min/week were 2496 in the CG and 2068 in the IG. There were no significant differences at the baseline visit in terms of physical activity between the groups.

Physical activity and clinical changes: 3 months

Table 3 reflects the changes in physical activity and clinical variables at 3 months compared to baseline measurements in the CG and the IG, and the differences between both groups, using the Student's *t*-test. In the CG, we found no changes in any of the recorded variables. In the IG, all of the variables measured by the pedometer improved, the METs-min/week consumed walking, the total METs-min/week and the time of sedentary lifestyle were reduced, as well as an improvement in the postprandial glycaemia, lipid profile and systolic blood pressure. The following significant increases were found in physical activity, comparing IG with CG: by 1852 mean daily steps, by 1623 aerobic steps, by 994 m in distance walked, total physical activity by 1297 METs-min/week. On the other hand, sedentary time decreased significantly by 34.3 minutes. In the biochemical variables, there was a significant improvement in the IG relative to the CG in BMI (−0.3 kg/m) and in the waist circumference (−2.3 cm) ($P<0.05$ for all).

Table 2. Physical activity in control group and intervention group.

	Baseline		3 Months		12 Months	
	CG	IG	CG	IG	CG	IG
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Pedometer						
Steps, mean/day[b,c]	8288 (4385)	8779 (4482)	8464 (4731)	10714 (4550)	8717 (5353)	10253 (4781)
Aerobic steps, mean/day[b]	3021 (3493)	3262 (3643)	3440 (3642)	5105 (4004)	3402 (3955)	4395 (4018)
Meters, mean/day[b]	3717 (2412)	4036 (2599)	3748 (2430)	5060 (2436)	4119 (3137)	4773 (2795)
Kilocalories, mean/day[b]	218 (167)	259 (170)	222 (172)	311 (204)	234 (202)	281 (194)
IPAQ						
METs intense PA	642 (2148)	216 (934)	407 (1600)	506 (2130)	221 (902)	209 (1189)
METs moderate PA	657 (1729)	438 (820)	419 (745)	506 (2130)	534 (1328)	691 (1428)
METs walking[b,c]	1197 (889)	1415 (1261)	1245 (955)	1920 (1193)	1113 (1021)	1606 (1153)
Total METs-min/week[b]	2496 (2892)	2068 (168)	2070 (1946)	2939 (2785)	1869 (2116)	2506 (2147)
Sedentary PA, min/day[c]	276 (138)	274 (137)	264 (149)	227 (129)	269 (166)	239 (145)

Variables are given as mean ± standard deviation.
A Student's *t*-test for independent samples was used for comparing the mean between the two groups.
[a]$P<0.05$ in the difference between the IG and the CG at the baseline.
[b]$P<0.05$ in the difference between the IG and the CG in the 3 months follow-up.
[c]$P<0.05$ in the difference between the IG and the CG in the 12 months follow-up.
CG: control group; IG: intervention group; PA: physical activity; IPAQ: international physical activity questionnaire; METs: metabolic equivalents.

Table 3. Changes at 3 months in physical activity and clinical variables.

	Changes in control group		Changes in intervention group		Mean difference (intervention-control)	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
Pedometer						
Steps, mean/day	−84	−698–531	1768**	1138–2399	1852**	975–2729
Aerobic steps, mean/day	156	−317–629	1779**	1248–2311	1623**	913–2333
Meters, mean/day	−35	−383–313	959**	639–1280	994**	524–1464
Kilocalories, mean/day	−3.7	−24.1–16.6	47.1**	19.4–74.8	50.8**	16.4–85.3
IPAQ						
METs intense physical activity	−236	−571–100	291	−140–721	527	−16–1069
METs moderate physical activity	−238	−570–93	75	−63–214	314	−44–671
METs walking	48	−106–202	505**	331–679	457**	226–688
Total METs/min/week	−426	−948–95	871**	343–1399	1297**	560–2035
Sedentary physical activity, min/day	−12.5	−39.0–14.1	−46.8**	−66.0 to −27.5	−34.3*	−66.9 to −1.8
Clinical variables						
Fasting plasma glucose, mg/dl	2.9	−1.9–7.8	−5.1	−12.3–2.2	−8.0	−16.7–0.7
Postprandial glucose, mg/dl	0.9	−4.6–6.4	−9.1*	−17.6 to −0.7	−10.0	−20.2–0.1
Glycated haemoglobin, %	0.1	−0.1–0.2	−0.1	−0.3–0.0	−0.2	−0.4–0.0
Total cholesterol, mg/dl	−2.2	−7.7–3.3	−5.4*	−10.0 to −0.8	−3.2	−10.3–3.9
LDL-cholesterol, mg/dl	−2.3	−7.4–2.8	−6.2**	−10.5 to −1.9	−3.9	−10.5–2.8
BMI, kg/m^2	−0.1	−0.3–0.2	−0.4**	−0.5 to −0.2	−0.3*	−0.6–0.0
Waist circumference, cm	0.4	−0.2–1.0	−1.9**	−2.5 to −1.2	−2.3**	−3.1 to −1.4
Systolic blood pressure, mmHg	−4.0	−10.2–2.2	−6.1**	−8.3 to −3.7	−2.0	−8.6–4.7
Diastolic blood pressure, mmHg	−0.5	−2.2–1.2	−2.1**	−3.7 to −0.5	−1.6	−3.9–0.7

A Student's *t*-test for paired data was used to assess change within the same group.
A Student's *t*-test for independent samples was used for comparing mean between the two groups.
*$p<0.05$; **$p<0.01$.
CI: confidence interval; IPAQ: international physical activity questionnaire; METs: metabolic equivalents; LDL: low-density lipoprotein; BMI: body mass index.

Table 4. Changes at 12 months in physical activity and clinical variables.

	Changes in control group		Changes in intervention group		Mean difference (intervention-control)	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
Pedometer						
Steps, mean/day	211	−556–979	1353**	646–2061	1142*	107–2177
Aerobic steps, mean/day	201	−402–804	1119*	542–1695	918*	89–1746
Meters, mean/day	323	−143–789	692*	335–1049	369	−204–941
Kilocalories, mean/day	8.4	−18.3–35.1	18.7	−7.6–45.0	10.3	−27.0–47.6
IPAQ						
METs intense physical activity	−421	−877–35	−6	−206–194	415	−80–910
METs moderate physical activity	−123	−498–252	253	−38–544	376	−96–848
METs walking	−83	−295–128	191	−32–414	274	−31–579
Total METs/min/week	−627*	−1242 to −13	438*	7–869	1065**	319–1811
Sedentary physical activity	−7.5	−39.1–24.1	−34.2**	−57.2 to −11.3	−26.7	−65.5–12.1
Clinical variables						
Fasting plasma glucose, mg/dl	3.8	−4.3–11.8	3.9	−3.1–10.8	0.1	−10.4–10.6
Post prandial glucose, mg/dl	0.8	−6.5–8.1	−7.1	−14.5–0.3	−7.9	−18.3–2.5
Glycated haemoglobin, %	0.1	−0.1–0.3	−0.1	−0.3–0.1	−0.2	−0.4–0.1
Total cholesterol, mg/dl	−2.0	−7.8–3.9	−4.2	−10.0–1.6	−2.2	−10.4–5.9
LDL-cholesterol, mg/dl	−6.0*	−10.8 to −1.1	−6.7*	−2.3–1.3	−0.7	−7.8–6.4
BMI, kg/m^2	−0.4**	−0.6 to −0.1	−0.3*	−0.5 to −0.1	0.1	−0.2–0.4
Waist circumference, cm	−0.2	−2.2–1.9	−1.0*	−0.2 to −2.3	−0.9	−3.0–1.3
Systolic blood pressure, mmHg	−5.6	−12.5–1.4	−7.2**	−9.8 to −4.6	−1.6	−8.9–5.6
Diastolic blood pressure, mmHg	0.0	−2.1–2.1	−1.5	−3.1–0.1	−1.5	−4.1–1.1

A Student's *t*-test for paired data was used to assess change within the same group.
A Student's t-test for independent samples was used for comparing mean between the two groups.
**p*<0.05; ***p*<0.01.
CI: confidence interval; IPAQ: international physical activity questionnaire; METs: metabolic equivalents; LDL: low-density lipoprotein; BMI: body mass index.

Physical activity and clinical changes: 12 months

Table 4 shows the changes in physical activity and in the clinical variables at 12 months relative to baseline measurements in the CG and the IG, and the differences between both groups, using the Student's *t*-test. In the CG at 12 months, total METs-min/week, LDL-cholesterol and BMI decreased. In the IG, the total daily steps, the aerobic steps, the distance walked and the total METs-min/week increased significantly, unlike the sedentary time which decreased; moreover, the significant differences in LDL-cholesterol, anthropometric parameters and systolic blood pressure remained. At 12 months, significant increases were still seen in the IG compared to the CG group by 1141 mean daily steps, by 917 aerobic steps and total physical activity by 1065 METs-min/week ($P<0.05$ for all). In terms of clinical variables, no significant differences were found between the groups.

In addition, using an ANCOVA adjusted to the baseline measurement, the proportion of IG subjects who walked at least 10,000 steps per day increased significantly by 13.4% at 3 months ($P<0.05$) and by 9.6% at 12 months. Moreover, the proportion of active IG subjects increased significantly by 5.9% at 3 months and by 5.9% at 12 months relative to baseline ($P<0.05$) (Figure 2).

Main findings

Using a repeated measures ANOVA, a significant effect of the intervention ($P<0.05$) was found between the study group (IG) in terms of change in mean daily steps, aerobic steps and total physical activity measured in METs-min/week over the 12-month follow-up period (Figure 3). In addition, sedentary time was shorter at each of the follow-up visits compared to baseline for both groups ($P>0.05$).

Figure 3 depicts the evolution of the different measures over time (baseline, 3 and 12 months) graphically. Statistical analysis indicates that the measures collected in mean daily steps and sedentary time did not vary significantly ($P>0.05$) throughout the evaluations in the CG but did in the IG ($P<0.01$). In the total METs-min/week, differences between the baseline visit and the follow-up visits at 3 and 12 months were found in the CG and in the IG.

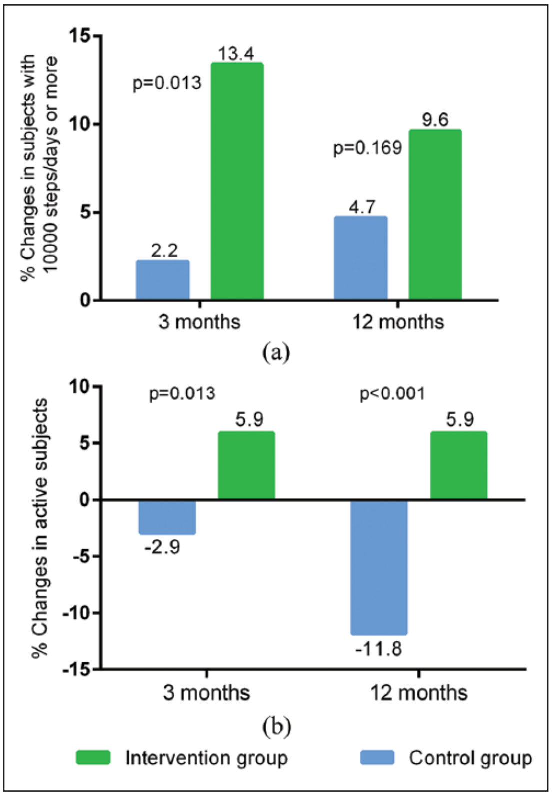

Figure 2. (a) Change from baseline in the mean proportion of subjects who walked more than 10,000 steps per day after 3 and 12 months in the intervention group (IG) and the control group (CG). (b) Change from baseline in the mean proportion of subjects who are active after 3 and 12 months IG and CG (analysis of covariance (ANCOVA) test). *P* value: measurements from the IG compared to the CG.

Discussion

The results of this study indicate that a multifactorial intervention strategy based on a smartphone app, heart-healthy walks and a diet workshop increased physical activity in patients with T2DM. Furthermore, this approach resulted in a short-term improvement in patient outcomes, as measured using clinically relevant biochemical indicators. These results can serve to help healthcare professionals facilitate successful, sustainable disease management strategies for patients with T2DM. This is a role particularly well suited for nurses, given how much time they spend with patients.

In line with the findings described here, studies published by Paula et al.[29] and Fayehun et al.[15] in patients with T2DM reported a significant daily increase of ,095 and 2913 steps, respectively. However, it should be noted that our results cannot be compared to those of the study be Fayehun et al.[15] because the baseline number of daily steps recorded in their experimental group (4551 ± 2397) was much lower than our IG (8779 ± 4482).

In addition, the IG in this study showed an increase in the number of aerobic steps in particular. This represents the only form of objective measurement using a pedometer of walking intensity and is, as such, highly relevant.[25] In general, studies do not assess the increase in the daily number of aerobic steps, despite the fact that the available evidence suggests that they are as centrally related to obesity and other metabolic issues as the total number of daily steps.[30]

With regard to self-reported physical activity, the increase in the METs-min/week consumed from intense activity is an important finding because it has been associated with a decreased risk of cardiovascular events, microvascular events and all-cause mortality in patients with T2DM.[4] A significant short and long-term reduction in sedentary time was also found in the IG. The importance of this finding is highlighted by a study from Duvivier et al.,[31] which concluded that one hour of moderate physical activity is insufficient to compensate for the potential negative effects of inactivity on insulin sensitivity and plasma lipids when the subject spends the rest of the day sitting. It has also been noted that shorter sitting times are related to postprandial increases in plasma insulin levels and decreases in glucose levels.[32]

Similar to our study, Arija et al.[33] showed an increase in physical activity of 775 METs-min/week in their experimental group, using supervised walks and sociocultural activities. In both studies, this increase was related to significant improvements in cardiovascular parameters including decreased waist circumference, BMI, systolic blood pressure, total cholesterol and LDL-cholesterol.

The present study showed that the differences in physical activity increase depending on the measurement method (i.e. pedometer or IPAQ). The same phenomenon occurred in a study conducted by Yates et al.,[34] in which they suggested that these differences could be due to the fact that the IPAQ measures periods of at least 10 minutes while the pedometer records total daily steps. In addition, the IPAQ is self-reported and may vary depending on subject recall and bias.

Our results lend support to previous studies on multifactorial interventions using mHealth in the general population. Kirwan et al.[35] reported a positive relationship between the use of a smartphone app and walking at least 10,000 steps per day. Using a multicomponent intervention similar to that described here, Glynn et al.[36] found a daily increase of 1631 total steps in their study group. Faridi et al.[37] also carried out a multicomponent intervention in patients with T2DM that included the use of a smartphone; however, their results showed a lower impact of their intervention on clinical variables and physical activity than described in this study.

This study has several limitations that should be considered when interpreting the results. First, because a multifactorial intervention was used it is impossible to know to what extent each component contributed to the changes observed in the study group. Moreover, the time of exposure to the intervention was short (3 months), we think that

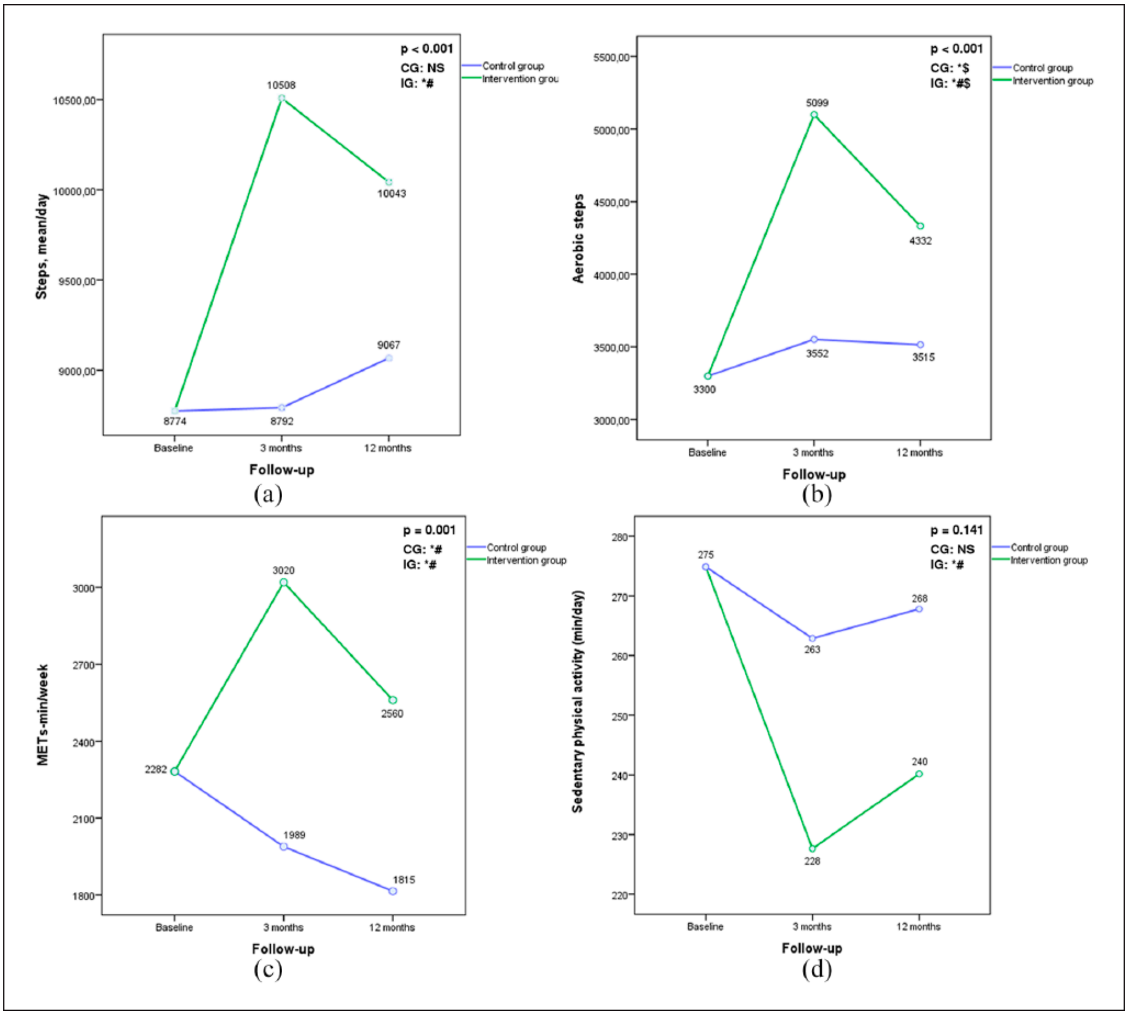

Figure 3. Changes from baseline to 3 and 12 months in (a) mean daily steps, (b) aerobic steps, (c) metabolic equivalent minutes per week (METs-min/week) and (d) sedentary time in the intervention group (IG) and the control group (CG) (repeated measures analysis of variance (ANOVA); IG n=91, CG n=81). Steps, mean per day: $P<0.001$; aerobic steps: $P<0.001$; METs-min/week: P=0.001; sedentary time (minutes per day): P=0.141. Values were adjusted relative to the baseline measurement. P value: effect of the intervention on the IG compared to the CG. NS: There are no significant differences between the three measures; *Differences between the baseline and 3-month follow-up visit; #Differences between the baseline and 12-month follow-up visit; $Differences between the follow-up visits at 3 and 12 months.

future studies should include reinforcement intervention during the period from 3 to 12 months and that this would be likely to improve the results. While physical activity could be measured objectively using a validated pedometer, sedentary time could only be determined subjectively with the IPAQ-S using self-reported data, which can be affected by recall and bias. We cannot be sure that during the study the subjects were not exposed to other forms of healthy advice. In addition, because of the nature of the intervention, participating subjects cannot be blinded. Also, while both groups were asked not to use other mobile apps focused on lifestyle improvement, we cannot guarantee that this was the case. Finally, in the heart-healthy walks, we cannot ensure that all subjects reached the heart rate required for their walk to be considered aerobic.

Conclusions

The multifactorial intervention described here, which included heart-healthy walks and a smartphone app, effectively increased the total METs-min/week and the mean daily steps in patients with T2DM. These results are promising and provide a basis for future multicentre studies with larger sample sizes that would enable assessment of more nuanced differences according to sex and age. These data can better inform future clinical approaches and app designs towards managing this increasingly prevalent disease and improving patient outcomes.

Implications for practice

- The multifactorial intervention used in the present study comprises one group meeting at a clinic, five aerobic walks and regular use of a smartphone application to improve lifestyles, and may be adapted for implementation in other settings (e.g. primary care).
- Our results support the clinical relevance of a multifactorial intervention as an additional complementary treatment to conventional management in patients with type 2 diabetes mellitus.
- Interventions that included smartphone applications seems to hold the potential to succeed by modifying physical activity levels and reducing sedentary time.

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Trial registration

ClinicalTrials.gov identifier: NCT02991079
(https://clinicaltrials.gov/ct2/show/NCT02991079)
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Declaration of conflicting interests

The authors declare that there is no conflict of interests.

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